



PTO/SB/08A (08-03)

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1

of

5

Complete if Known

Application Number	10/055,863
Filing Date	January 22, 2002
First Named Inventor	Engler, Heidrun
Art Unit	1632
Examiner Name	Wilson
Attorney Docket Number	016930-000816US

U.S. PATENT DOCUMENTS+

Examiner Initials*	Cite No. ¹	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
CP	1	5,013,556	A	05-07-1991	Woodle et al.	
CP	2	5,108,921	A	04-28-1992	Low et al.	
CP	3	5,166,320	A	11-24-1992	Wu et al.	
CP	4	5,213,804	A	05-25-1993	Martin et al.	
CP	5	5,279,833	A	01-18-1994	Rose	
CP	6	5,283,185	A	02-01-1994	Epand et al.	
CP	7	5,334,761	A	08-02-1994	Gebeyehu et al.	
CP	8	5,346,701	A	09-13-1994	Heiber et al.	
CP	9	5,521,291	A	05-28-1996	Curjel et al.	
CP	10	5,542,935	A	08-06-1996	Unger et al.	
CP	11	5,552,309	A	09-03-1996	March	
CP	12	5,554,386	A	09-10-1996	Groman et al.	
CP	13	5,578,475	A	11-26-1996	Jessee	
CP	14	5,580,859	A	12-03-1996	Felgner et al.	
CP	15	5,589,466	A	12-31-1996	Felgner et al.	
CP	16	5,601,818	A	02-11-1997	Freeman et al.	
CP	17	5,631,236	A	05-20-1997	Woo et al.	
CP	18	5,804,566	A	09-08-1998	Carson et al.	
CP	19	6,210,939	B1	04-03-2001	Gregory et al.	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
CP	20	WO	92/06180		04-16-1992			<input type="checkbox"/>
CP	21	WO	93/14188		07-22-1993			<input type="checkbox"/>
CP	22	WO	93/19768		10-14-1993			<input type="checkbox"/>
CP	23	WO	93/20221		10-14-1993			<input type="checkbox"/>
CP	24	WO	94/06922		03-31-1994			<input type="checkbox"/>
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CP	26	WO	95/11984		05-04-1995			<input type="checkbox"/>
CP	27	WO	97/05209		02-13-1997			<input type="checkbox"/>
CP	28	WO	97/27599		07-31-1997			<input type="checkbox"/>

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		Art Unit	1632		
		Examiner Name	Wilson		
Sheet	2	of	5	Attorney Docket Number	016930-000816US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
fy	29	Abe, A. et al., "Transduction of a drug-sensitive toxic gene into human leukemia cell lines with a novel retroviral vector" PSEBM 203:354-359 (1993)	
fy	30	Arteaga, C. et al., "Tissue-targeted antisense c-fos retroviral vector inhibits established breast cancer xenografts in nude mice" Cancer Research 56:1098-1103 (1996)	
fy	31	Aungst, B. and Rogers, N., "Comparison of the effects of various transmucosal absorption promoters on buccal insulin delivery" Inter. J. Pharmac. 53:227-235 (1989)	
fy	32	Banerjee, A. et al., "Changes in growth and tumorigenicity following reconstitution of retinoblastoma gene function in various human cancer cell types of microcell transfer of chromosome 13" Cancer Research 52:6297-6304 (1992)	
fy	33	Bass, C. et al., "Recombinant adenovirus-mediated gene transfer to genitourinary epithelium in vitro and in vivo" Cancer Gene Ther. 2(2):97-104 (1995)	
fy	34	Blixt, Y. et al., "Enhancement of intracellular uncoating of adenovirus in HeLa cells in the presence of benzyl alcohol as a membrane fluidizer" Arch. Virol. 129:265-277 (1993)	
fy	35	Boulikas, "Gene therapy of prostate cancer: p53, suicidal genes, and other targets" Anticancer Research 17:1471-1506 (1997)	
fy	36	Brewster, S. et al., "Gene therapy in urological oncology: principles, strategies and potential" Eur. Urol. 25:177-182 (1994)	
fy	37	Cairns, P. et al., "Loss of heterozygosity at the RB locus is frequent & correlates with muscle invasion in bladder carcinoma" Oncogene 6:2305-2309 (1991)	
fy	38	Cancer Facts & Figures 1995, Am. Canc. Soc. 5-11 (1995)	
fy	39	Cooper, M. et al., "Safety-modified episomal vectors for human gene therapy" PNAS USA 94:6450-6455	
fy	40	Curiel, D. et al., "Adenovirus enhancement of transferring-polylysine-mediated gene delivery" PNAS USA 88:8850-8854 (1991)	
fy	41	Dalesandro, J. et al., "Cardiac and pulmonary replacement" J. Thoracic Cardio. Surg. 111(2):416-422 (1996)	
fy	42	Fujimoto, K. et al., "Frequent association of p53 gene mutation in invasive bladder cancer" Cancer Research 52:1393-1398 (1992)	
fy	43	Ginsberg, H. et al. "Role of early region 3 (E3) in pathogenesis of adenovirus disease" PNAS USA 86:3823-3827 (1989)	
fy	44	Good, N. et al., "Hydrogen ion buffers for biological research" Biochemistry 5(20):467-477 (1966)	

Examiner Signature	<i>E. Keller</i>	Date Considered	9/29/05
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		Filing Date	January 22, 2002		
		First Named Inventor	Engler, Heidrun		
		Art Unit	1632		
		Examiner Name	Wilson		
Sheet	3	of	5	Attorney Docket Number	016930-000816US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
✓	45	Goodrich, D. et al., "Expression of the retinoblastoma gene product in bladder carcinoma cells associates with a low frequency of tumor formation" Cancer Research 52:1968-1973 (1992)	
✓	46	Greenberg, R. et al., "Intravesical AD32 (N-trifluoroacetyladiamycin-14-valerate) in the treatment of patients with refractory bladder carcinoma- clinical efficacy, pharmacology and safety" Proc. Am. Urol. Assoc. 153(supp 233a):19 (1995)	
✓	47	Grenney, H. et al., "Characterization of imidazoline binding protein(s) solubilized from human brainstem: studies with [³ H] idazoxan and [³ H]clonidine" Neurochem. Int. 25(2):183-191 (1994)	
✓	48	Helenius et al., "Properties of Detergents" In: Methods in Enzymology, Vol. 56, 734-749 (1979)	
✓	49	Hemstrom, C. et al., "Gene product of region E4 of adenovirus type 5 modulates accumulation of certain viral polypeptides" J. Virol. 62(9):3258-3264 (1988)	
✓	50	Huang, S. et al., "A cellular protein that competes with SV40T antigen for binding to the retinoblastoma gene product" Nature 350:160-162 (1991)	
✓	51	Janout, V. et al., "Evidence for highly cooperative binding between molecular umbrella-spermine conjugates and DNA" Bioconjugate Chem. 8:891-895 (1997)	
✓	52	Janout, V. et al., "Molecular umbrellas" J. Am. Chem. Chem. Soc. 118:1573-1574 (1996)	
✓	53	Ji, W. et al., "Inhibition of hepatitis B virus by retroviral vectors expressing antisense RNA" J. Viral. Hep. 4:167-173 (1997)	
✓	54	Kaneda, Y. et al., "Prevention of restenosis by gene therapy" Annals N.Y. Acad. Sci. 811:299-310 (1997)	
✓	55	Koc, O. et al., "Transfer of drug resistance genes into hemotopoietic progenitors to improve chemotherapy tolerance" Sem. Oncol. 23(1):46-64 (1996)	
✓	56	Langer et al., "Biocompatible controlled release polymers for delivery of polypeptides and growth factors" J. Cell Biochem. 45:340-345 (1991)	
✓	57	Lee, R. et al., "Lipidic vector systems for gene transfer" Crit. Rev. Ther. Drug Carrier Sys. 14(2):173-206 (1997)	
✓	58	Li, Q. et al., "Assessment of recombinant adenoviral vectors for hepatic gene therapy" Hum. Gene. Ther. 4:403-409 (1993)	
✓	59	Makarov, S. et al., "Suppression of experimental arthritis by gene transfer of interleukin 1 receptor antagonist cDNA" PNAS USA 93:402-406 (1996)	
✓	60	Marshall, E., "Gene therapy's growing pains" Science 269:1050-1055 (1995)	

Examiner Signature	<i>E. K. Wilson</i>	Date Considered	8/29/04
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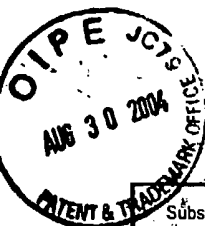
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✓	61	Miller, N. et al., "Targeted vectors for gene therapy" FASEB J. 9:190-199 (1995)	
✓	62	Monson, F. et al., "Indigocamine as a quantitative indicator of urothelial integrity" J. Urol. 145:842-845 (1991)	
✓	63	Morris, B. et al., "Adenoviral-mediated gene transfer to bladder in vivo" J. Urol. 152:506-509 (1994)	
✓	64	Murayama, Y. et al., "Antisense oligonucleotides to p53 tumor suppressor suppress the induction of apoptosis by epidermal growth factor in NCI-H 596 human lung cancer cells" Antisense Nucl. Acid Drug Devel. 7:109-114 (1997)	
✓	65	Niidome, T. et al., "Binding of cationic α -helical peptides to plasmid DNA and their gene transfer abilities into cells" J. Biol. Chem. 272(24):15307-15312 (1997)	
✓	66	Nolta, J. et al., "Transduction of pluripotent human hematopoietic stem cells demonstrated by clonal analysis after engraftment in immune-deficient mice" PNAS USA 93:2414-2419 (1996)	
✓	67	Parsons, C. et al., "Bladder surface glycosaminoglycans: an epithelial permeability barrier" J. Urol. 143:139-142 (1990)	
✓	68	Pinnaduwege, P. et al., "Use of a quarternary ammonium detergent in liposome mediated DNA transfection of mouse L-cells" Biochim. Biophys. Acta 985:33-37 (1989)	
✓	69	Plank, C. et al., "The influence of endosome-disruptive peptides on gene transfer using synthetic virus-like gene transfer systems" J. Biol. Chem. 269(17):12918-12924 (1994)	
✓	70	Raper, S. et al., "Safety and feasibility of liver-directed ex vivo gene therapy for homozygous familial hypercholesterolemia" Annals Surgery 223(2):116-126 (1996)	
✓	71	Rosenberg, S. "The immunotherapy and gene therapy of cancer" J. Clin. Oncol. 10(2):180-199 (1992)	
✓	72	Ross et al., "Gene therapy in the United States: a five-year status report" Human Gene Therapy 7:1781-1790 (1996)	
✓	73	Sandberg, J. et al., "Improving access to intestinal stem cells as a step toward intestinal gene transfer" Human Gene Therapy 5:323-329 (1994)	
✓	74	Shawaphun et al., "Chemical evidence for transbilayer movement of molecular umbrellas" J. Am. Chem. Soc. 121:5860-5864 (1999)	
✓	75	Spandidos, D. et al., "Expression of the normal H-ras1 gene can suppress the transformed and tumorigenic phenotypes induced by mutant ras genes" Anticancer Research 10:1543-1554 (1990)	
✓	76	Takahashi, R. et al., "The retinoblastoma gene functions as a growth and tumor suppressor in human bladder carcinoma cells" PNAS USA 88:5257-5261 (1991)	

Examiner Signature	<i>E. Perle</i>	Date Considered	9/29/03
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SP	77	Verma et al., "Gene therapy- promises, problems and prospects" Nature 389:239-242 (1997)	
SP	78	Vidal, P. et al., "Nouvelle stratégie pour vectorisation d-ARN dan des cellules de mammifères. Utilisation d'un vecteur peptidique" CR Acad. Sci. III 32:279-287 (1997)	
SP	79	Wills, K. et al., "Development and characterization of recombinant adenoviruses encoding human p53 for gene therapy of cancer" Hum. Gene Ther. 5:1079-1088 (1994)	
SP	80	Wills, K. et al., "Gene therapy for hepatocellular carcinoma: Chemosensitivity conferred by adenovirus-mediated transfer of the HSV-1 thymidine kinase gene" Cancer Gene Ther. 2(3):191-197 (1995)	
SP	81	Wu, G. et al., "Receptor-mediated gene delivery and expression in vivo" J. Biol. Chem. 263(29):14621-14624 (1988)	
SP	82	Xiao, X. et al., "Adeno-associated virus (AAV) vector antisense gene transfer in vivo decreases GABA _A α ₁ containing receptors and increases inferior collicular seizure sensitivity" Brain Res. 756:76-83 (1997)	
SP	83	Yew, N. et al., "Optimization of plasmid vectors for high-level expression in lung epithelial cells" Human Gene Therapy 8:575-584 (1997)	

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